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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,770	12/29/2000	Kuber T. Sampath	00960-520PRO	7664

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BOSTON, MA 02110-2624

EXAMINER
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WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/581,770

Applicant(s)

SAMPATH ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-19 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

Claims 1-5 and 7-10 will not be considered in the election/restriction because the examiner cannot determine what these claims encompass. Claims 1-5 and 7-10 do not contain active process steps or materials that would complete the pre-amble of the claims. The step "activating" is a consequence of an action performed by the one of skill in the art. The claims are missing an active process step, e.g., the step of exposing the cells to an agonist.

Claims 14-17 will not be considered in the election/restriction because the examiner cannot determine what these claims encompass. Claims 14-17 do not contain active process steps or materials that would complete the pre-amble of the claims. The step "inhibiting" is a consequence of an action performed by the one of skill in the art. The claims are missing an active process step, e.g., the step of exposing the cells to an inhibitor.

If claims 1-5, 7-10, and 14-17 are amended in the response to the election/restriction and the examiner can determine what the claims encompass, then the examiner will consider whether the claims are directed to the elected invention or a non-elected invention.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 6, 18, and 19, drawn to a method for restoring cellular phenotype in a cell affected by disease, damage, or age, the method comprising the step of administering a compound consisting of a morphogen.

Group II, claim(s) 11, 12, and 13, drawn to a method for restoring cellular phenotype in a cell affected by disease, damage, or age, the method comprising the step of transfecting the cell with a compound consisting of a DNA encoding a Smad protein.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said

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product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

Unity of inventions does not exist because each group is directed to a different product that is structurally and functionally different than the product listed in the other groups.

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Accordingly, Groups I-II are not so linked by the same corresponding or a corresponding technical feature as to form a single general inventive concept.

If the applicants elect either Group I or Group II, another restriction is required under 35 USC 372.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single inventive concept under PCT rule 13.1.

The species are as follows:

(a) the individual morphogen listed in claim 19 (select one);

(b) a DNA encoding a Smad1 protein, Smad2 protein, Smad3 protein, Smad4, Smad5, or Smad8 protein.

Applicant is required, in reply to this action, to elect a single species [from a) or b) depending on the elected group] from the species elected to which the claims shall be restricted if no generic claim is finally held allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 6, 18, 19, and claims dependent therefrom correspond to the species of (a).

Claim 11, 12, 13 and claims dependent therefrom correspond to the species of (b).

The following claim(s) are generic, claims 6, 11, and 18.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the species of (a) the morphogens listed above are different structurally and/or functionally with regard to their site of action, and the PCR Rules for Lack of Unity do not apply; (b) the DNA sequences listed above are different structurally and/or functionally with regard to their site of action, and the PCR Rules for Lack of Unity do not apply.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

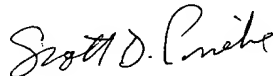
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER